510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

1. **SUBMITTER'S NAME**
   Toshiba America Medical Systems, Inc.

2. **ADDRESS**
   2441 Michelle Drive
   Tustin, CA. 92780-2068

3. **CONTACT PERSON**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

4. **TRADE NAME(S):**
   INFX-8000V with 56 inch Monitor

5. **COMMON NAME:**
   Solid State X-Ray Imager (Flat Panel/Digital Imager)

6. **DEVICE CLASSIFICATION:**
   Class II (per 21 FR 892.1650)

7. **PRODUCT CODE / DESCRIPTION:**
   MQB – Image-Intensified Fluoroscopic X-ray System

8. **PERFORMANCE STANDARD:**
   21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

9. **DEVICE DESCRIPTION:**
   The main function of this system is to perform fluoroscopy /radiography of the interventional angiography system. Using the fluorescent scintillation effect of X-rays that have passed through the patient's body, image information is obtained for medical diagnosis treatment.

10. **SUMMARY OF INTENDED USES:**
    This system is a diagnostic X-ray system designed for multidirectional observation of the flow of the contrast medium injected into the blood vessels of the patient. This system is intended for use in diagnostic and interventional procedures involving the cardiac blood vessels, abdominal blood vessels, and lower limb blood vessels.

11. SUBSTANTIAL EQUIVALENCE:

The INFX-8000V with 56 inch Monitor is of comparable type and is substantially equivalent to the INFX-8000V (K081582).

12. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1 standards and its collateral standards. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via an initial report.

13. CONCLUSION

The INFX-8000V complies with the same or equivalent standards and has the same intended use as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Toshiba Medical Systems Corporation, Japan
% Mr. Paul Biggins
Director Regulatory Affairs/US Agent
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 94780

AUG 2 0 2013

Re: K112054
Trade/Device Name: INFX-8000V with 56 inch monitor
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified flouroscopic x-ray system
Regulatory Class: II
Product Code: JAA and IZI
Dated: July 15, 2011
Received: July 19, 2011

Dear Mr. Biggins:

This letter corrects our substantially equivalent letter of August 5, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: INFX-8000V with 56 inch monitor

Indications for Use:

This device is a digital radiography/fluoroscopy system used in a diagnostic angiography configuration. This system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen and lower extremities.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K112054